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Hundreds Die Every Year From Chemotherapy Overdoses Because Doctors Don't Order Simple Gene Test

Hundreds of cancer patients every year die excruciating deaths from overdoses of common chemotherapy drugs because doctors rarely order a simple gene test — required by European health agencies but not the FDA — that could identify those at risk.

By KFF Health News

12

Chemotherapy
Dispense with Medication Guide attached or provided separately
Lot # 022992
point of view
Overdose
drug or other
too much of
than

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By Arthur Allen

One January morning in 2021, Carol Rosen took a standard treatment for metastatic breast cancer. Three gruesome weeks later, she died in excruciating pain from the very drug meant to prolong her life.

Rosen, a 70-year-old retired schoolteacher, passed her final days in anguish, enduring severe diarrhea and nausea and terrible sores in her mouth that kept her from eating, drinking and eventually speaking. Skin peeled off her body. Her kidneys and liver failed.

"Your body burns from the inside out," said Rosen's daughter, Lindsay Murray, of Andover, Massachusetts.

Rosen was one of more than 275,000 cancer patients in the U.S. who are infused each year with fluorouracil, known as 5-FU, or, as in Rosen's case, take a nearly identical drug in pill form called capecitabine.

These common types of chemotherapy are no picnic for anyone, but for patients who are deficient in an enzyme that metabolizes the drugs, they can be torturous or deadly.

Those patients essentially overdose because the drugs stay in the body for hours rather than being quickly metabolized and excreted.

The drugs kill an estimated 1 in 1,000 patients who take them — hundreds each year — and severely sicken or hospitalize 1 in 50.

Doctors can test for the deficiency and get results within a week — and then either switch drugs or lower the dosage if patients have a genetic variant that carries risk.

Yet a recent survey found that only 3% of U.S. oncologists routinely order the tests before dosing patients with 5-FU or capecitabine.

That's because the most widely followed U.S. cancer treatment guidelines — issued by the National Comprehensive Cancer Network — don't recommend preemptive testing.

The U.S. Food and Drug Administration (FDA) added new warnings about the lethal risks of 5-FU to the drug's label on March 21 following queries from KFF Health News about its policy. However, it did not require doctors to administer the test before prescribing the chemotherapy.

The agency, whose plan to expand its oversight of laboratory testing was the subject of a U.S. House of Representatives hearing, also on March 21, has said it could not endorse the 5-FU toxicity tests because it's never reviewed them.

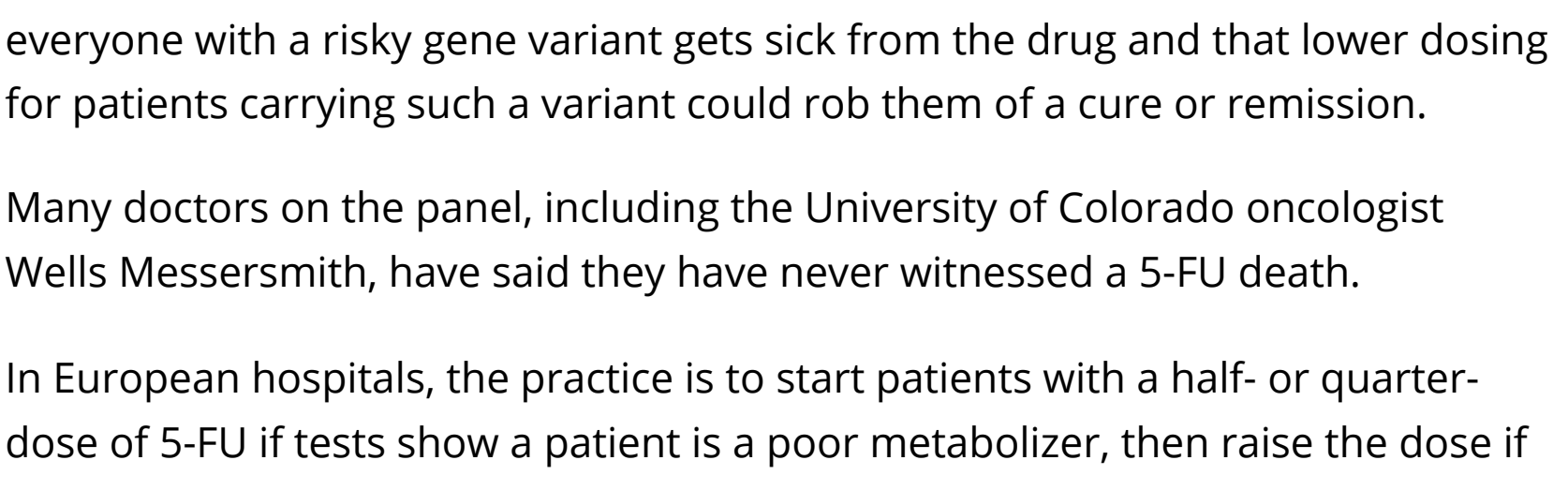
But the FDA at present does not review most diagnostic tests, said Daniel Hertz, an associate professor at the University of Michigan College of Pharmacy.

For years, with other doctors and pharmacists, he has petitioned the FDA to put a black box warning on the drug's label urging prescribers to test for the deficiency.

"FDA has responsibility to assure that drugs are used safely and effectively," he said.

The failure to warn, he said, "is an abdication of their responsibility."

The update is "a small step in the right direction, but not the sea change we need," he said.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Europe ahead on safety

British and European Union drug authorities have recommended the testing since 2020.

A small but growing number of U.S. hospital systems, professional groups and health advocates, including the American Cancer Society, also endorse routine testing.

Most U.S. insurers, private and public, will cover the tests, which Medicare reimburses for $175, although tests may cost more depending on how many variants they screen for.

In its latest guidelines on colon cancer, the Cancer Network panel noted that not everyone with a risky gene variant gets sick from the drug and that lower dosing for patients carrying such a variant could rob them of a cure or remission.

Many doctors on the panel, including the University of Colorado oncologist Wells Messersmith, have said they have never witnessed a 5-FU death.

In European hospitals, the practice is to start patients with a half- or quarter-dose of 5-FU if tests show a patient is a poor metabolizer, then raise the dose if the patient responds well to the drug.

Advocates for the approach say American oncology leaders are dragging their feet unnecessarily, and harming people in the process.

"I think it's the intransigence of people sitting on these panels, the mindset of 'We are oncologists, drugs are our tools, we don't want to go looking for reasons not to use our tools,'" said Gabriel Brooks, an oncologist and researcher at the Dartmouth Cancer Center.

Oncologists are accustomed to chemotherapy's toxicity and tend to have a "no pain, no gain" attitude, he said. 5-FU has been in use since the 1950s.

Yet "anybody who's had a patient die like this will want to test everyone," said Robert Diasio of the Mayo Clinic, who helped carry out major studies of the genetic deficiency in 1988.

Oncologists often deploy genetic tests to match tumors in cancer patients with the expensive drugs used to shrink them. But the same can't always be said for gene tests aimed at improving safety, said Mark Fleury, policy director at the American Cancer Society's Cancer Action Network.

When a test can show whether a new drug is appropriate, "there are a lot more forces aligned to ensure that testing is done," he said. "The same stakeholders and forces are not involved" with a generic like 5-FU, first approved in 1962, and costing roughly $17 for a month's treatment.

Oncology is not the only area in medicine in which scientific advances, many of them taxpayer-funded, lag in implementation.

For instance, few cardiologists test patients before they go on Plavix, a brand name for the anti-blood-clotting agent clopidogrel, although it doesn't prevent blood clots as it's supposed to in a quarter of the 4 million Americans prescribed it each year.

In 2021, the state of Hawaii won an $834 million judgment from drugmakers it accused of falsely advertising the drug as safe and effective for Native Hawaiians, more than half of whom lack the main enzyme to process clopidogrel.

The fluoropyrimidine enzyme deficiency numbers are smaller — and people with the deficiency aren't at severe risk if they use topical cream forms of the drug for skin cancers.

Yet even a single miserable, medically caused death was meaningful to the Dana-Farber Cancer Institute, where Carol Rosen was among more than 1,000 patients treated with fluoropyrimidine in 2021.

Her daughter was grief-stricken and furious after Rosen's death.

"I wanted to sue the hospital. I wanted to sue the oncologist," Murray said. "But I realized that wasn't what my mom would want."

Instead, she wrote Dana-Farber's chief quality officer, Joe Jacobson, urging routine testing. He responded the same day, and the hospital quickly adopted a testing system that now covers more than 90% of prospective fluoropyrimidine patients.

About 50 patients with risky variants were detected in the first 10 months, Jacobson said.

Dana-Farber uses a Mayo Clinic test that searches for eight potentially dangerous variants of the relevant gene. Veterans Affairs hospitals use an 11-variant test, while most others check for only four variants.

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Different tests may be needed for different ancestries

The more variants a test screens for, the better the chance of finding rarer gene forms in ethnically diverse populations.

For example, different variants are responsible for the worst deficiencies in people of African and European ancestry, respectively. There are tests that scan for hundreds of variants that might slow the metabolism of the drug, but they take longer and cost more.

These are bitter facts for Scott Kapoor, a Toronto-area emergency room physician whose brother, Anil Kapoor, died in February 2023 of 5-FU poisoning.

Anil Kapoor was a well-known urologist and surgeon, an outgoing speaker, researcher, clinician and irreverent friend whose funeral drew hundreds. His death at age 58, only weeks after he was diagnosed with stage 4 colon cancer, stunned and infuriated his family.

In Ontario, where Kapoor was treated, the health system had just begun testing for four gene variants discovered in studies of mostly European populations.

Anil Kapoor and his siblings, the Canadian-born children of Indian immigrants, carry a gene form that's apparently associated with South Asian ancestry.

Scott Kapoor supports broader testing for the defect — only about half of Toronto's inhabitants are of European descent — and argues that an antidote to fluoropyrimidine poisoning, approved by the FDA in 2015, should be on hand.

However, it works only for a few days after ingestion of the drug and definitive symptoms often take longer to emerge.

Most importantly, he said, patients must be aware of the risk.

"You tell them, 'I am going to give you a drug with a 1 in 1,000 chance of killing you. You can take this test. Most patients would be, 'I want to get that test and I'll pay for it,' or they'd just say, 'Cut the dose in half.'"

Alan Venook, the University of California-San Francisco oncologist who co-chairs the National Comprehensive Cancer Network, has led resistance to mandatory testing because the answers provided by the test, in his view, are often murky and could lead to undertreatment.

"If one patient is not cured, then you giveth and you taketh away," he said. "Maybe you took it away by not giving adequate treatment."

Instead of testing and potentially cutting a first dose of curative therapy, "I err on the latter, acknowledging they will get sick," he said.

About 25 years ago, one of his patients died of 5-FU toxicity and "I regret that dearly," he said. "But unhelpful information may lead us in the wrong direction."

In September 2023, seven months after his brother's death, Kapoor was boarding a cruise ship on the Tyrrhenian Sea near Rome when he happened to meet a woman whose husband, Atlanta municipal judge Gary Markwell, had died the year before after taking a single 5-FU dose at age 77.

"I was like … that's exactly what happened to my brother," said Kapoor.

Murray senses momentum toward mandatory testing. In 2022, the Oregon Health & Science University paid $1 million to settle a suit after an overdose death.

"What's going to break that barrier is the lawsuits, and the big institutions like Dana-Farber who are implementing programs and seeing them succeed," she said.

"I think providers are going to feel kind of bullied into a corner. They're going to continue to hear from families and they are going to have to do something about it."

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Arthur Allen, senior correspondent for KFF Health News, writes about the FDA, the pharmaceutical industry and COVID-19-related topics.

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Best Newest Oldest

BarbaraCharis
a month ago

Chemo posions the body and destroys the Immune System...It is a miracle, when people survive it. You don't kill cancer...you must stop feeding it ...the food it loves in order for it to grow. I did this twice and tumors disappeared!!! No money to be made in the truth...so hide it.

7 0 Reply

Peter van der Stam ↗ BarbaraCharis
a month ago

Good on you Barbara,
My wife was told, she had only 5 years to live if she refused more radiation and on top of that Chemo.
Instead, she went to a homeopath who got her immune system going again and she survived another 40+ years. So much for poison.
But also, let's face it, if medicine would do what they are for, big pHARMa would not earn much anymore.

3 0 Reply

fromaway46 ↗ BarbaraCharis
a month ago

What food did you stop feeding it ?

1 0 Reply

BChristine ↗ fromaway46
a month ago

The list is long ... processed sugar, seed oils, any fast food - including most restaurant food, even 'somewhat' healthy conventional food which is full of pesticides and toxic chemicals ... those are just off the top of my head!

1 0 Reply

digo ↗ fromaway46
a month ago

How to Starve Cancer, a book by Jane McLelland goes over this in great detail. There are different diets and foods to avoid based on the type of cancer you have. Was recommended by Paul Marik MD on one of his podcasts.

0 0 Reply

Robin Bell
a month ago

Chemo"therapy" is poison. It doesn't matter what "genes" you have or don't have. Poison is not the answer to cancer.

5 0 Reply

BChristine
a month ago

Chemo(therapy) is definitely poison to the body. Some people do survive it, but if root health issues are not addressed (food and lifestyle choices), it will most likely return. I have seen this happen to several people who thought they were "cured" from chemo(therapy).

3 0 Reply

BChristine
a month ago

I believe this is what happened to my former husband who I loved to the bitter end. He was being treated with chemo for metastatic lung cancer which had spread to the liver. He had survived the 1st round in Summer of 2020 and was doing okay; but then they wanted to start him with more intense treatment in October. I tried my best to talk him out of it because he was already in a weak state and I felt he wasn't near strong enough ... but he was told by the doctor this next treatment would "prolong his life". He had one (maybe two) treatments before he collapsed and died mid November.

I don't know how some of these "doctors" sleep at night. He was ***clearly*** not strong enough for this intense chemo(therapy); yet it was pushed on him. You couldn't pay me enough to take any kind of chemo(therapy) if I were to have a cancer diagnosis.

3 0 Reply

Someone
a month ago

Not surprised in the least bit. Chemo is a poison and why anyone would allow a drug that burns the skin to go into their veins is beyond me. It's a miracle anyone survives chemo and most cancer deaths are actually from chemo, not the cancer. Most oncologists would refuse chemo if they got cancer and it's all about the money so why would they order a test that would result in them making less money by lowering doses when they could have ordered a safer and still effective treatment to start with?

1 0 Reply

Laura Pieters
a month ago

Once again money and not health is driving medical decisions. Very sad.

1 0 Reply

lanainutahdesert
a month ago

It's all so extraordinarily primitive. Technologies involving sound waves and light waves should have been developed decades ago to deal with illnesses like cancer in the body. Chemotherapy and surgery are the height of barbarism.

0 0 Reply

tony
a month ago edited

Gee Wally, I'm confused… aren't there proven alternatives to treating cancer that avoid chemo? Why did Aunt Betsy have to die? Well Beaver, Aunt Betsy believed in the doctors protocols and assured us that it must be safe or the govt wouldn't allow it to be used. Dang Wally, even I know those people can't be trusted and I'm just a dumb kid….

https://www.burzynskiclinic...

0 0 Reply

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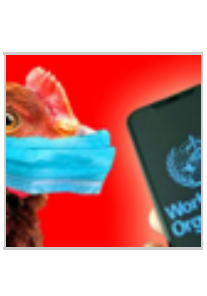
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